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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,764	03/12/2002	John Andrew Chaddock	1581.0900000/RWE/MTT	2729
26111	7590	07/28/2005		
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/070,764

Applicant(s)

CHADDOCK ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-45 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-45 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 04/29/05 in response to the non-final Office Action mailed 02/01/05. With this, Applicants have amended the specification.

Status of Claims

- 2) Claims 1-40 have been canceled via the amendment filed 04/29/05.
New claims 41-45 have been added via the amendment filed 04/29/05.
Claims 41-45 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the specification made in paragraph 6 of the Office Action mailed 02/01/05 is withdrawn in light of Applicants' amendments to the specification.

Rejection(s) Moot

- 6) The rejection of claim 37 and those dependent therefrom made in paragraph 7 of the Office Action mailed 02/01/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claims.
- 7) The rejection of claims 22-30 and 37-40 made in paragraph 9(a) of the Office Action mailed 02/01/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.
- 8) The rejection of claims 23 and 24 made in paragraph 9(b) of the Office Action mailed 02/01/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of

Applicants' cancellation of the claims.

- 9) The rejection of claims 29 and 30 made in paragraph 9(c) of the Office Action mailed 02/01/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.
- 10) The rejection of claim 22 made in paragraphs 9(d) and 9(h) of the Office Action mailed 02/01/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 11) The rejection of claims 23-26 made in paragraph 9(e) of the Office Action mailed 02/01/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.
- 12) The rejection of claims 23-25 made in paragraph 9(f) of the Office Action mailed 02/01/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.
- 13) The rejection of claim 30 made in paragraph 9(h) of the Office Action mailed 02/01/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 14) The rejection of claim 37 made in paragraphs 9(i) and 9(j) of the Office Action mailed 02/01/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 15) The rejection of claims 23-30 and 38-40 made in paragraph 9(k) of the Office Action mailed 02/01/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.
- 16) The rejection of claims 22-24 and 27-29 made in paragraph 11 of the Office Action mailed 02/01/05 under 35 U.S.C. § 102(b) as being anticipated by Rossetto *et al.* (*Biochem. J.* 285: 9-12, 1992), is moot in light of Applicants' cancellation of the claims.
- 17) The rejection of claims 25 and 26 made in paragraph 13 of the Office Action mailed 02/01/05 under 35 U.S.C. § 103(a) as being unpatentable over Rossetto *et al.* (*Biochem. J.* 285: 9-12, 1992) as applied to claim 22 above, and further in view of Hallis *et al.* (*In: Botulism and Tetanus*

Neurotoxins. (Ed) DasGupta BR *et al.* Plenum Press, New York, pages 433-436, 1993), is moot in light of Applicants' cancellation of the claims.

New Rejection(s) Based on Applicants' Amendment

The new rejection(s) set forth below are necessitated by Applicant's amendments or submission of new claims.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

18) Claim 41 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claim 41 includes the limitations: 'method of removing a clostridial toxin from a preparation comprising'; 'applying said preparation ...'; 'binding said clostridial toxin to the first ligand, thereby forming an immobilized ligand-toxin complex and an eluate, wherein said eluate may contain ligand-toxin complex that has become detached from the first affinity column'; and 'obtaining a preparation that is substantially free from clostridial toxin'. Applicants point to page 9, second paragraph to page 10, line.20 and Example 3 of the instant specification as providing descriptive support to the new claim(s). Example 3 is however limited to the production of LH_N/A fragment from BoNT/A by antibody-affinity chromatography and preparation of an anti-BoNT/A antibody-affinity column. Broad limitations such as 'a preparation' and 'a clostridial toxin' encompassing any clinical or non-clinical preparation with or without containing LH_N/A fragment and any clostridial toxin other than botulinum toxin are not supported in the instant specification. Furthermore, there appears to be no descriptive support in the instant specification for limitations: 'forming an immobilised ligand-toxin complex and an eluate' and 'contacting said eluate a second ligand immobilized present in the eluate'. There appears to be no descriptive support for a method comprising the recited part (ii). Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to specific pages and lines providing the descriptive support in the specification as originally filed, for the new limitations, or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

19) Claims 41-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 41 is vague and indefinite in the limitation: 'substantially free from clostridial toxin', because the specification does not provide a standard for ascertaining the requisite degree for the recited preparation that qualifies as being 'substantially free from clostridial toxin'. The metes and bounds of the claim are indeterminate.

(b) Claim 41 is vague, indefinite and confusing in the phrase: 'selectively binds to the clostridial toxin to form an immobilized ligand-toxin complex ... binding said clostridial toxin to the first ligand'. It is unclear whether or not the binding in step (i) and the binding in step (ii) represent two different binding steps. It is further unclear whether binding recited in part (ii) is a function of the first ligand as recited in part (i), or a step to be performed after the applying step of part (i) and before the contacting step of part (iii) or obtaining step of part (iv) of the claim.

(c) Claim 41 is further vague and indefinite in the limitation: '(ii) binding said clostridial toxin', because it is unclear whether this represents selective binding as in part (i) or non-selective binding.

(d) Claim 41 is further vague and indefinite in the limitation: 'eluate **may** contain ligand-toxin complex wherein said second ligand selectively binds to ligand-toxin complex **present** in the eluate' [Emphasis added]. The term 'may' in part (ii) does not positively imply that the ligand-toxin complex is definitely present in the eluate as recited at the end of part (iii). The scope of the claim is internally inconsistent.

(e) Claim 41 appears to lack antecedent basis in the limitation: 'ligand-toxin complex' (see line 9). Is this ligand-toxin complex different from the one recited in the earlier parts of the claim?

(f) Claim 41 appears to lack antecedent basis in the limitation: 'ligand-toxin complex'

(see line 14). Is this ligand-toxin complex different from the one recited in part (ii)?

(g) Claim 41 is vague and confusing in the limitations: 'said second ligand selectively binds to ligand-toxin complex' (see lines 13 and 14), because it is unclear whether the second ligand binds to the ligand part of the ligand-toxin complex or the toxin part of the ligand-toxin complex.

(h) Claim 41 appears to lack proper antecedent basis in the limitation: 'clostridial toxin' (see last line). Is this 'clostridial toxin' different from the one recited in parts (i), (ii), and line 1 of the claim?

(i) Claim 41 is vague and indefinite in the limitation: 'binds the clostridial toxin to form an immobilized ligand-toxin complex', because it is unclear how a specific toxin, 'clostridial toxin', can give rise to a 'toxin' complex upon binding with a ligand. Note that the limitation 'toxin' is of much broader scope than the narrower limitation: 'clostridial toxin'.

(j) Claims 42-45, which depend from claim 41, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

20) Claims 41-45 stand rejected.

21) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

22) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for

submission of after-final amendments is (571) 273-8300.

23) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

24) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

July, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER